A COMPARATIVE STUDY ON EFFECTIVENESS OF ACAPELLA ON IMPROVING LUNG FUNCTION IN CHRONIC ASTHMA

Dissertation work submitted to

THE TAMIL NADU DR. M. G. R. MEDICAL UNIVERSITY,

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Degree programme

Submitted by

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Dissertation work entitled

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Under the guidance of

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CHENNAI-32.

Project work evaluated on ----------

Internal Examiner External Examiner

CERTICATE I

This is to certify that the dissertation work entitled **"A COMPARATIVE STUDY ON EFFECTIVENESS OF ACAPELLA ON IMPROVING LUNG FUNCTION IN CHRONIC ASTHMA"**

was carried out by **Reg. no.27102327** P.P.G College of physiotherapy, Coimbatore-35, affiliated to The Tamilnadu Dr. M.G.R medical university, Chennai-32, under the guidance

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ABSTRACT

Study Objective: To examine the effectiveness of acapella along with conventional therapy in improving Lung function in chronic asthma.

Participants: 30 subjects with chronic asthma were selected. They were divided into control group and experimental group with 15 patients each.

Outcome measure: The outcome measurement is done by peak expiratory flow meter (PEFM) and medical research clinical dyspnoea scale (MRC)

Result: Both groups showed significant improvement in lung function after the therapy program .The experimental group showed a statistically significant improvement in pulmonary function when compared to the control group at 5 % level of significance.

Conclusion: Treatment with the – acapella along with conventional physiotherapy showed a significant improvement in lung function and dyspnoea than control group. It can be used as an effective treatment in improving the expiratory flow rates .A well designed trial is needed to study the effectiveness of acapella in improving lung function in a large group and to know its long term effect.

Keywords: Acapella, Chronic Asthma, Dyspnoea, Lung function

CHAPTER I

1.1 INTRODUCTION

Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular mast cells, eosinophils, T lymphocytes, neutrophils and epithelial cells. This inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness and cough **(Jessica H. Boyd and Robert C. Strunk).**

Asthma is a very common disease with immense social impact. The prevalence of asthma has increased significantly since the 1970s. As of 2009, 300 million people were affected world wide. It is estimated that asthma has 7-10% prevalence worldwide. While asthma is a more common in affluent countries, it is by no means a restricted problem; the WHO estimate that there are between 15 and 20 million people with asthma in India. Striking increases in asthma prevalence have been observed in populations migrating from a rural to an urban one.

Asthma occurs at all ages but predominantly in early life that one half of the cases develop before age of 10 and another third occur before the age of 40. In childhood there is 2:1 male/female preponderance, but sex ratio equalizes by age 30 **(Gina – 2006).**

Asthma is characterized by several changes in the airways including smooth muscle hyperplasia, thickening of the basement membrane, and denudation of epithelial cells, airway tissue edema and mucosal gland hypertrophy.

Airway inflammation plays a central role in asthma this contributes to airflow limitations through bronchus constriction, mucus production and airway edema. Allergic inflammation characterized by increased levels of immunoglobulin E, stimulates and immune response driven by TH2 lymphocytes, which activate mast cells, macrophages and other proinflammatory mediators. This cascade leads to the contraction of smooth muscles in the airway, increased secretion of mucus into the airway and vasodilatations of airway vessels. **(Chiappara – 2001)**

The airway inflammation in asthma leads to variable levels of lower airway obstruction that affects both the small and large airways. Recurrent airflow limitation is caused by bronchoconstriction, airway edema, chronic mucus plug formation and airway remodelling. Airway hyper responsiveness is associated with airway inflammation and underlies the presentation of symptoms in asthma. Hyper responsiveness not only contributes the symptoms of bronchoconstriction and airflow limitations, but also has been shown to be associated with a decline in lung function**. (Lauren Robertson et al – 2007)**

In asthma airway remodelling represents the healing and alterations in the airway that occurs due to chronic inflammation. Mucus glands are increased in number, affecting the thickness of the airway wall and increase in mucus secretion. The inflammatory exudates that increase surface tension and promote closure of airway. The reticular basement membrane also becomes thickened with deposition of collagens, these changes results in increasing thickness of airways and exaggerates the airway obstruction.

Traditionally physiotherapy applies various techniques and modalities, chest clapping or cupping has been replaced by the use of inflatable vests or mechanical vibrators applied to the chest. Oral devices that apply positive end expiratory pressure maintain the patency of the airway during exhalation and accomplish many of the same goals as postural drainage in a shorter time and with less discomfort. Chest physiotherapy forms an integral part of the management of bronchial secretions. There are several chest physiotherapy techniques or devices aimed at removing bronchial secretions **(Jennifer.A.Pryor – 2008).** The oscillatory positive expiratory pressure device plays an important role in bronchial hygiene, which consists of a mechanical oscillatory device called the acapella **(Alves.C.E -2010)**. It is an easy to use physiotherapy device, combines safe endobronchial positive expiratory pressure with vibratory and oscillatory effects. Vibratory devices work by oscillating vibrations that travel into the lungs. The acapella is a hand held device causing an oscillatory positive expiratory pressure within the airways, has been proposed as an alternative to more conventional airway clearance techniques **(A.J.Ragavan – 2010).**

The peak expiratory flow is one component of the flow volume manoeuvre. This has been encouraged by the availability of simple devices for its measurement .It also provides a tool for patients to use to monitor their asthma objectively **(Ma Lourdes – 2004).**

Dyspnoea can be measured in a variety of ways. The Medical research council dyspnoea breathlessness score is self administrated, grades dyspnoea during walking according to five levels, with grade 5 representing patients who consider themselves home bound due to breathlessness.

1.2. NEED OF THE STUDY

The major goal of a physiotherapist is to optimize a patient's lung function. Increasing lung volume causes a reduction in airway resistance and improves ventilation. The acapella breathing treatment is a form of bronchial hygiene therapy for patients who are having trouble in clearing secretions from the airway. Normal airway clearance requires an effective cough with ciliated epithelial cells that move mucus towards the trachea and larynx where the excess secretion can be expectorated. Respiratory physiotherapy is essential to the treatment of all acute or chronic respiratory disorders in which expectoration difficulties are major problems.

This study is focused on the restoration of lung volumes normal by oscillatory positive expiratory pressure, its effectiveness in asthma using acapella and to examine its effectiveness in the management of asthmatics independently for airway mucus clearance and improvement in lung function and reducing dyspnoea of patients with chronic asthma.

1.3. OPERATIONAL DEFINITION

ASTHMA:

Asthma is a disease characterized by increased responsiveness of the bronchi to various stimuli, manifested by widespread narrowing of the airways that changes in severity either spontaneously or as a result of treatment (**Robert.L.Souhami).**

DYSPNOEA:

It is defined by the American thoracic society as the subjective sensation of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity **(American thoracic society).**

ACAPELLA (Oscillatory positive expiratory pressure device):

It is a hand held device that combines the resistive features of a positive expiratory pressure with oscillation and can be used in virtually any spatial orientation, a device that combines the oscillations of air within the airways during expiration and a positive expiratory pressure therapy **(Alves.C.E).**

PEAK EXPIRATORY FLOW RATE

The peak expiratory flow rate measures how fast a person can breathe out (exhale) air. It is one of many tests that measures how lung well working**.(Andrew Schriber)**

1.4. AIM OF THE STUDY

To examine the effectiveness of acapella an oscillatory positive expiratory pressure device to be more helpful than conventional physiotherapy for airway mucus clearance, in improving lung function.

1.5. OBJECTIVES OF THE STUDY

1. To find out the effectiveness of Acapella along with conventional physiotherapy in improving pulmonary function in chronic asthma patients

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2. To establish the effectiveness of Acapella along with conventional physiotherapy in improving lung function in chronic asthma patients.

1.6. HYPOTHESIS

ALTERNATE HYPOTHESIS:

Conventional physiotherapy with the acapella is more effective than conventional physiotherapy in improving lung function in patients with chronic asthma.

NULL HYPOTHESIS:

Conventional physiotherapy with acapella is not more effective than conventional physiotherapy in improving lung function in patients with chronic asthma.

CHAPTER II
REVIEW OF LITERATURE

1) World Health Organisation (2005-2006): Asthma is a chronic disease characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person. During an asthma attack, the lining of the bronchial tubes swells, causing the airways to narrow and reducing the flow of air into and out of the lungs.

2) Global Initiative For Asthma (2005): Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation causes an associated increase in airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at the night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment

4) Gina (2009): Asthma is one of the most common chronic diseases with an estimated 300 million individuals affected world wide. Its prevalence is increasing, especially among children

5) Stephen T. Holgate (2008): Airway inflammation in asthma is a multicellular process involving mainly eosinophils, neutrophils, T lymphocytes and mast cells with eosinophillic infiltration the most striking feature. As the disease becomes more severe and chronic the inflammatory infiltrate spreads more proximally and distally. In chronic asthma the number of goblet cells that secrete the viscous mucus increases, with parallel reduction in ciliated cells. Since mucus production is fundamental to the pathogenesis of chronic asthma, this metaplastic change in the airway epithelium is of great importance in the more peripheral airways which are devoid of goblet cells.

6) Nakagome. et.al. (2011): Bronchial asthma is a chronic disorder characterized by airway inflammation, reversible airway obstruction, and airway hyper responsiveness. Eosinophills are believed to play an important role in the pathogenesis of asthma

through the release of inflammatory mediators. In severe asthma, not only eosinophils but also mast cells or neutrophils play important roles. Mast cells are much infiltrated to smooth muscle in severe asthma and induce airway remodelling by release of inflammatory mediators

7) Joanne Douglas M (2005):

It has been long recognized that asthma is a disease of eosinophilic airway inflammation. In patients with airway inflammation is suggested by -Charcot Leyden crystals (derived from the cytoplasm of the eosinophills) Creola bodies (clumps of desquamated epithelial cells)

Crushmann spirals (twisted casts of airways consists of glycoprotein's cores around which many fibrils are bound).Increased mast cells activation in the airways and subsequent degranulation.Mast cells release cytokines and chemokines that recruit eosinophils, basophills and T-lymphocytes to the local mucosa.

Ongoing inflammation results in structural changes within the airways .This leads to as airway remodelling and includes epithelial damage, basement membrane thickening and hypertrophy of smooth muscle and mucus glands, leading to increased bronchial hyper responsiveness and airflow obstruction.

8) Gina (2006):

Airway narrowing is the final common pathway leading to symptoms and physiological changes in asthma. Several factors contribute to development of airway narrowing in asthma; airway smooth muscle contraction, airway edema, airway thickening and mucus hypersecretion.

9) Orihara K. (2009): Tissue remodelling is now an integral element of asthma pathophysiology. Pathophysiology of asthma generally inflammatory, immune and structural cells as well as a wide range of mediators. An intricate network of mediators, released from both immune and inflammatory cells.

10) Jennifer Pryor (2008): The main problem in asthma is a chronic inflammatory process within the airway resulting in recurrent episodes of wheezing, breathlessness and cough, There is increased responsiveness of the smooth muscles in the bronchial walls to various stimuli. Hypertrophy of the mucus glands may lead to mucus

plugging .These changes cause variable airway obstruction which may become chronic and severe.

11) Nancy et al (1990): Three measurements of PEFR were obtained by using calibrated mini-Wrights peak flow meter. PEFR was strongly related to age, sex and, height. After adjustments for these factors, low PEFR was associated with chronic respiratory symptoms cough, wheeze, and shortness of breath, exertional dyspnoea, orthopnoea and paroxysmal nocturnal dyspnoea. PEFR was strongly related to measures of functional ability and physical activity, self-assessment of health and simple measures of cognitive function.

12) Tsukiokak (2001): Peak Expiratory Flow Meter: Controlling drugs and relieving drugs as prescribed for many of the patients and they use their drugs when their symptoms are getting worse. Patients tent to underestimate their symptoms, since they cannot evaluate their airway obstruction correctly. It is known that patients with out PEFM are at a higher risk of dying from asthma. This attempts to infer the significance of peak expiratory flow and peak flow meter especially in the management of adult asthmatics.

13) Ma Lourdes. B (2004): Cost effectiveness and cost-benefit analysis reveal that, a peak flow based asthma education and self-management plan is the most effective alternative in reducing costs associated with ER visits and hospitalization due to asthma exacerbation.

14) Peter.J. Barnes (2002): An important tool for the diagnosis and subsequent treatment of asthma is the use of peak expiratory flow meters to measure peak expiratory flows. PEF is a simple, reproducible index and can be measured with inexpensive and portable PFM. For most asthmatic patients PEF monitoring should be done at least in morning or awakening and in the evening hrs .Its also useful in assessing the severity of asthma and its response to treatment. Its effort dependent and mainly caliber of large airways and therefore underestimate the degree of airflow limitation in peripheral airways .A diurnal variability of more than 20% is diagnostic of asthma. PEF reflects the patency of central airways and thus may underestimate the airflow limitation particularly in the peripheral airways.

15) Darbee et al (2006):

The MRC Dyspnoea scale is an easy to use tool to document the impact of dyspnoea on a persons physical functioning. It has acceptable reliability and validity for use as a measurement tool and is sensitive to change. As such, this outcome measure provides clinicians with the ability to quantify dyspnoea and to monitor changes in dyspnoea in response to physical therapy interventions.

16) Martinez et al (2003):

Dyspnoea is a main feature of symptomatology in asthma, and its perception does not necessarily correlates well with airway obstruction. MRC and Borg clinical dyspnoea scales showed significant information in subjects with asthma.

17) Roland Buhl et al [2010]: MRC dyspnoea scale is a simple and standardized method of categorizing disability. The patient selects a grade on the self-applied 5-point instrument that describes everyday situations or activity levels provoking breathlessness and impairment.

18) BTS (2001):

Patient selection for pulmonary rehabilitation-

The benefits of rehabilitation may apply to all patients with dyspnoea from respiratory disease, the introduction rehabilitation become appropriate when patients become aware of their disability, some patients with cardiac or locomotors disability may not benefit as much

19) Anna Murphy (2007): Pulmonary rehabilitation involves exercise training, counselling, and education. The exercise component of the program is personalized to the patient's capabilities and individual goals. Current guidelines states that the exercise component of pulmonary rehabilitation should consist of aerobic exercises to achieve generalized strengthening of the peripheral muscles.

20) Jennifer. A. Pryor (2008): Pulmonary rehabilitation is an effective therapy, pulmonary rehabilitation programme results in; Improvement in exercise tolerance,

Improvement in the sensation of dyspnoea, Improvement in the ability to perform activities of daily living, Improvement in health related quality of life, Improvement in muscle strength, endurance masses and Reductions in number of days spent in the hospital. Pulmonary Rehabilitation is considered to be an important therapeutic intervention.

21) Alves C.E. (2010):

Mechanical Analysis of an Oscillatory Positive Expiratory Pressure device used in Respiratory Rehabilitation: Acapella® Blue device produces oscillation in the ranges of ciliary movements and respiratory system resonance frequency of patients with respiratory diseases. This aims to characterize the mechanical behaviour, blue, a respiratory rehabilitation device designed to aid in sputum clearance .In this peak to peak oscillation amplitude (App) and peak frequency (fp) and positive pressure level (ppl), in the flow range more commonly found in practice. The parameters were evaluated in all 5 adjustment levels of the equipment in intervals of 50 ml/s.The device may produce oscillation in the ranges of ciliary movements and respiratory system resonance frequency of patients with respiratory diseases .Data obtained in this work help to optimize the use of the acapella blue device in respiratory rehabilitation.

22) A.J.Ragavan (2010): The study demonstrated superimposed oscillations at high frequency generated by the acapella device resulted in significant increases in displacement of mucus during cough. Acapella vibrates the airways internally loosening the mucus that can be coughed out. Clearance of airway mucus during cough is most effective with more gel - like mucus with airflow oscillations.

23) Magady A.H. et al (2010): Evaluation of the single and combined roles of oscillatory positive expiratory device and conventional chest physiotherapy techniques in mechanically ventilated chronic obstructive pulmonary disease patients. Acapella device is a good to daily chest physiotherapy procedures in mechanically ventilated with high success rate and can replace the exhausting, costly and time consuming conventional procedures in such patients.

24) Carlos Eduardo Alves (2009):

Acapella device may produce clinically adequate values of mean pressure and oscillation frequency. However it depends on its use at optimized conditions. The user friendly software proposed in this study could help the user to achieve these conditions.

25) Janet E. Patterson (2005):

Airway clearance in Bronchiectases “A randomized crossover trial of ACBT versus Acapella. Acapella is as effective a method of airway clearance as ACBT and may offer a user-friendly alternative to ACBT for patients with bronchiectasis.

CHAPTER III

MATERIALS AND METHODOLOGY

3.1 MATERIALS

Acapella (OPEP) Blue and Green

Pillow

Sputum cup

Evaluation chart

Data collection sheet

Consent form

Chronic Asthma questionnaire form.

Peak Expiratory Flow Chart

Medical Dyspnea Clinical Research Scale

3.2 METHODOLOGY

3.2.1 Study Design

The Research approach for the study was an experimental study design.

3.2.2 Study Sample

Non probability convenient sampling technique method will randomly assigned to experimental and control group of 15 subjects each.

3.2.3 Sample Size

Sample size consists of 30 chronic asthma subjects.

3.2.4 Study Method

Group A (Control group) - receives conventional physiotherapy.

Group B (Experimental group) - receives conventional physiotherapy with the acapella device.

3.2.5 Selection Criteria

Inclusion Criteria :

- Age group between 50 to 60 years
- Chronic asthma patient selected according to the chronic asthma questionnaire.
- Both male and female patients.

Exclusion Criteria :

- Active seizures
- Active haemoptysis
- Epistaxis
- Nausea.
- Increased intracranial pressure
- Mental or cognitive impairments
- Patients who are under regular bronchodilator drugs.
- Patients with any cardiovascular problems.
- Uncontrolled hypertension and hypotension
- Patients with any neurological problems.
- Patients with infectious disease like tuberculosis and bacterial infections
- Pulmonary edema and pulmonary embolism.
- Patients with musculoskeletal problems.

3.2.6 Study Setting

S.H.Medical Centre Kottayam

3.2.7 Duration of study

Total duration of study is six months

3.2.8 Parameters

Peak Expiratory Flow Meter values

MRC dyspnoea scale values

3.2.9 Statistical Tool

Non-parametric statistical tests

Mann Whitney "U" Test.

Wilcoxon Signed Rank Tests.

Parametric test namely:

Two Sample "t" tests

Paired "t" test

Mann Whitney "U" Test:

This is a non-parametric test for testing whether two population means are equal. This test is applied on the pretest scores of group A and group B to confirm that the two independent samples were homologous and thereby to make the results obtained acceptable. This tests was applied on the post test scores of group A and group B to confirm that the two independent groups show a significant difference in the results obtained and thereby, to find the effectiveness of the treatment intervention over the other group.

$$U = n_1 n_2 + n_1 \frac{(n_2+1)}{2} - R_1$$

Where n_1, n_2 are sample sizes,

R_1 be the sum of the ranks given to the observations in the Group A.

Calculate the value of "U"

Wilcoxon Signed Rank Test:

This test is used for testing whether two population means are equal in the case of related samples that is analysing the pre and post-test values of Group A and also of Group B separately to conclude whether the treatment intervention is effective or not. We consider the differences $d_i = x_i - y_i$, where xi and yi are the values before and after treatment for the ith individual. Then assign ranks to these differences ignoring signs. Then assign the respective signs to the ranks Find the sum of positive ranks and sum of negative ranks say T+ and T-.

Then Wilcoxon statistic is,

$$W = \text{Mean}(T+, T-).$$

Calculate the value of W or corresponding value of Z

Two-Sample t Test:

This test is used for testing the equality of means of two groups

Test statistic used is,

The test statistic used is,

$$t = \frac{\bar{x}_1 - \bar{x}_2}{\sqrt{\frac{n_1 s_1^2 + n_2 s_2^2}{n_1 + n_2 - 2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}}$$

This follows a "t" distribution with (n1+n2-2) degrees of freedom

Here x_1 = sample mean of Group A.

x_2 = sample mean of Group B.

s_1 = sample variance of Group A.

s_2 = sample variance of Group B.

n_1 = sample size of Group A.

n_2 = sample size of Group B.

Calculate the value of "t" and look at the significance level. If the significance level is less than 0.05 we reject the null hypothesis at 5% level of significance

Paired "t" test:

This test is used for testing the equality of means of Group A and Group B.

The test statistic used is,

$$t = \frac{\bar{d}\sqrt{n-1}}{sd}$$

That follows a t distribution with (n) degrees of freedom.

Here $d_i = x_i - y_i$. Xi and y_i are the values before and after the treatment and d_i is the AM of the d values.

Sd is the SD of the d values and n is the sample size.

Calculate the value of the test statistic "t" and look at the significance level .If the significance level is less than 0.05 we reject the null hypothesis at 5% level of significance.

3.2.10 Techniques

(GROUP A) Control Group

Received conventional physiotherapy which includes,

Education :(5 minutes)

Educating the patient and family about the technique for smoking cessation and the dangers associated with smoking; patients should be encouraged to quit smoking. Education regarding the preventive measures such as on keeping pets outdoors, on using a mask for dusty jobs, avoiding spray polishes, exposure to pollutants and on avoiding certain foods that are allergic.

Relaxation Positions :(10 minutes)

Educate the patients regarding the relaxed positions to be adopted during an attack of breathlessness. The relaxation positions for a breathless patient are in

- High side-lying
- Forward lean sitting
- Relaxed sitting
- Forward lean standing
- Relaxed standing

Breathing Techniques :(10-Minutes)

Pursed lip breathing- The patient is instructed to inhale through the nose and exhale slowly through the pursed lips. So encourage the patient to use pursed lip breathing especially in dyspnoeic episodes to reduce the difficulty of breathing. (5 times per session).

Breath Control During Walking :(5 Minutes)

Teaching correct breathing pattern with expiration to inspiration ratio 2:1, and expiration for the first two steps and inspiration for the next one step.

Chest Mobility Exercises: (10 Minutes)

To mobilize the upper chest and shoulders -The patient is seated and the shoulders are flexed to 180 degrees with slight abduction (hands up) with inspiration and bend forward at the hips and reach the floor during expiration.(5 times per session)

Trunk Rotation- Patient in standing position and rotate the trunk to both sides in corporation PLB (5 times per session).

GROUP B (Experimental Group):

Received conventional treatment for 40 minutes, along with oscillatory positive expiratory pressure device acapella which included for 20 minutes.

Acapella Device:

Procedure:

Select the device (the acapella is available in two color coded models). The green acapella is high frequency model for patients able to maintain an expiratory flow for 15 LPM or greater for three seconds. The blue acapella is low frequency model for patients not capable of maintaining an expiratory flow of 15 LPM for 3 seconds.

With the first use of the acapella, ensure that the frequency adjustment dial is turned counter - clockwise to the lowest frequency - resistance setting. Frequency\Resistance increase clockwise. Selecting the proper resistance range produces the desired I: E ratio 1:3 to 1:4.

Place the mouth piece light in mouth; maintain a tight seal on the mouth piece during inspiration. Use/apply nose clip if necessary. Instruct the patient to relax performing diaphragmatic breathing. Patient should inspire the volume of air greater than normal tidal volume but less than total lung capacity. Instruct the patient to

slowly inhale ¾ maximum breathing capacities. Instruct the patient to hold breath 2-3 seconds. Direct the patient to exhale to functional residual capacity (FRC) actively, but not too forcefully through the device. Emphasize the importance of inhaling slowly, breath holding and suppressing the urge to cough. The patient should be able to exhale for 3-4 seconds while the device vibrates if the patient cannot maintain an exhalation for this length of time, adjust the dial clockwise. Clockwise adjustment increases the resistance of the vibrating orifice, which will allow the patient to exhale at low flow rate. Perform 10-20 breaths. Remove mouth piece and perform 2-3 “huff” coughs to raise secretions as needed. Repeat the steps 4-10 as prescribed .This is repeated about 4 to 6 times for 10-20 minutes treatment. Document procedure and relevant findings on the respiratory progress notes in the therapy section of the chart.

The patient performed the acapella between 1-5 dialed settings, or a setting that was tolerated by the patient. The acapella settings were increased once the patient can achieve 3 seconds of continuous expiration.

The inspiratory phase is followed by a slow prolonged exhalation.
Device is not gravity dependent and can be performed in conjunction with postural drainage. Device can be used in line with aerosol \nebulizer treatments. No care giver is needed once technique is mastered and independence promoted.

Acapella Cleaning Instructions:

There are four parts to the device and it comes out easily. Remove the mouth piece. Lift cover by pressing forefinger and thumb along ribbed surfaces by mouthpiece, it opens to a 90 degree angle. Gently remove cover from base. Lift out rocker assembly which is white, this is one piece. You should now have four individual parts. Soak in warm soapy water. Rinse thoroughly. Air dry all 4 parts do it not less than once weekly

3.2.11 Procedure

Prior sanction was obtained from the authorities to conduct the study. All patients after satisfying the inclusion criteria for the study .The patients and the bystanders are explained in detail about the procedure and the patients who are willing to take part in the study a consent form is signed by the patient itself.

30 chronic asthma patients who are fulfilling the inclusion criteria will be assigned using non- probability convenient sampling and are randomly assigned into two groups namely control group (Group A) and experimental group (Group B).Each group contains 15 patients each. Group A receives conventional physiotherapy for 40 minutes. Group B receives conventional physiotherapy for 40 minutes plus 20 minutes of the acapella device to improve lung function.

The treatment schedule consists of 3 weeks, six days per week and daily. The tool selected for pre-test and post-test measurements of pulmonary function testing was using the peak expiratory flow rate and for grading breathlessness, MRC dyspnea scale.

OUTCOME MEASUREMENT

Assessment Procedure

A) Peak Expiratory Flow Meter: To Use The PFM.

1. Insert the mouth piece into the meter, if not already fitted. Ensure the pointer is set at zero (L/min).
2. Hold the PFM so that your fingers are clear of the scale and slot. Do not obstruct the holes at the end of the PFM.
3. Stand up if possible (or) sitting preferably, take a deep breath, place the peak flow meter in the mouth and hold horizontally, closing the lips around the mouth piece, then blow as hard and as fast as you can.
4. Note the number on the scale indicated by the pointer.
5. Return the pointer to zero (L/min) and repeat the procedure twice move to obtain three readings. Mark the highest of the three readings on your peak flow chart

6. Measure your peak flow rate close to the same time each day. You should record the PFR twice daily.
7. Keep a chart of your PFR.
8. Chart the highest of the three readings. This is called “your personal best “

Measurement:

The best of three readings is used as the recorded value of the peak expiratory flow rate. Peak flow readings are often classified into 3 zones of measurement according to the American Lung Association.

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According to American Lung Association, green zone represents 80-100 %of your usual normal PFR signals all clear. Yellow zone represents 50-80% 0f your usual or normal PFR signals caution. Red zone indicates less than 50 % of your usual or normal PFR signals a medical alert.

- MRC dyspnea scale is used to assess the severity of Asthma.

CHAPTER IV

DATA PRESENTATAION

GROUP: A – CONTROL GROUP

	PEAK EXPIRATORY FLOW RATE		MRC DYSPNOE SCALE	
Sl. No.	Pre Test	Post Test	Pre Test	Post Test
1	300	325	3	2
2	290	320	3	2
3	305	330	4	3
4	310	330	3	2
5	295	320	4	3
6	290	315	4	3
7	315	345	3	2
8	300	340	3	2
9	320	350	3	2
10	315	355	3	2
11	325	360	4	3
12	295	320	4	3
13	310	340	3	2
14	330	365	2	1
15	325	350	3	2

GROUP: B – EXPERIMENTAL GROUP

	PEAK EXPIRATORY FLOW CHART		MRC DYSPNOE SCALE	
Sl. No.	Pre Test	Post Test	Pre Test	Post Test
1	305	375	3	1
2	300	360	4	2
3	295	355	4	2
4	310	390	3	1
5	290	360	4	2
6	315	370	3	1
7	300	365	3	1
8	295	360	3	1
9	320	400	3	1
10	330	410	2	1
11	325	400	3	1
12	310	390	3	1
13	325	400	2	1
14	295	360	4	2
15	315	385	4	2

CHAPTER V

DATA ANALYSIS AND INTERPRETATION

Analysis of Post PEFR scores of control and experimental groups using two sample t test

TABLE 1

Group	N	Post Test		T
		Mean	SD	
Control	15	337.67	16.132	6.438
Experimental	15	378.67	18.657	

For control group mean is 337.67 and standard deviation is 16.132 For the experimental group mean is 378.67 and standard deviation is 18.657 .The “t” value obtained is 6.438,which is statistically significant at 0.05 level of significance .The post PEFR scores of the control group are less than that of the scores of the experimental group. This means that the acapella along with conventional physiotherapy and conventional physiotherapy alone differ significantly in improving expiratory flow rates in chronic asthma

ANALYSIS OF POST MRC VALUES OF CONTROL AND EXPERIMENTAL GROUPS USING MANN- WHITNEY U TEST

TABLE 2

Group	N	Mean Rank	Sum of rank	U
Control	15	20.83	312.50	32.500
Experimental	15	10.17	152.50	

The post test scores taken at the end of 3 weeks treatment

For the control group mean rank is 20.83, sum of rank is 312.50.For the experimental group mean rank is 10.17, and sum of rank is 152.50. ”U”value obtained is 32.500 which are statistically significant at 0.05 level of significance. In this case post MRC scale of control group is greater than that of the corresponding scores at experimental group at 5% level of significance. There is significant difference between the post MRC scores of the two groups at 5% level of significance. This means that acapella along with conventional physiotherapy and conventional physiotherapy alone differs significantly in their effectiveness in improving breathlessness.

ANALYSIS OF PRE AND POST MRC VALUES OF CONTROL GROUP USING WILCOXON SIGNED RANK TEST

TABLE 3

Score	Mean	N	Mean Rank		Sum of Rank		Z
			Negative	Positive	Negative	Positive	
Pre	3.27	15	8.00	0.00	120.00	0.00	3.873
Post	2.27	15					

Mean pre test score for control group is 3.27 and mean post test score for Control group is 2.27. Z value obtained is 3.873. which is statistically significant at 5%level of significance .That is the pre MRC score differ significantly from post MRC score at 5% level of significance .It can be seen that the MRC scale of post test score is less than pre test score at 5% level of significance .Data analysis shows significant improvement in breathlessness of experimental group .This might be due to the cumulative effect of conventional physiotherapy.

ANALYSIS OF PRE AND POST MRC VALUES OF EXPERIMENTAL GROUP USING WILCOXON SIGNED RANK TEST

TABLE 4

Score	Mean	N	Mean Rank		Sum of Rank		Z
			Negative	Positive	Negative	Positive	
Pre	3.20	15	8.00	0.00	120.00	0.00	3.690
Post	1.33	15					

Mean pre test score for experimental group 3.20 and mean post test score for experimental group is 1.33. Z value obtained is 3.690. This is statistically significant at 5% level. That is the pre MRC score differs significantly from post MRC scores at 5% level of significance. It can be seen that the MRC scale post test score are less than pre test score at 5% level of significance. Data analysis show significant improvement in breathlessness of experimental group. This might be due to the oscillatory positive expiratory pressure along with conventional physiotherapy

GRAPH 1

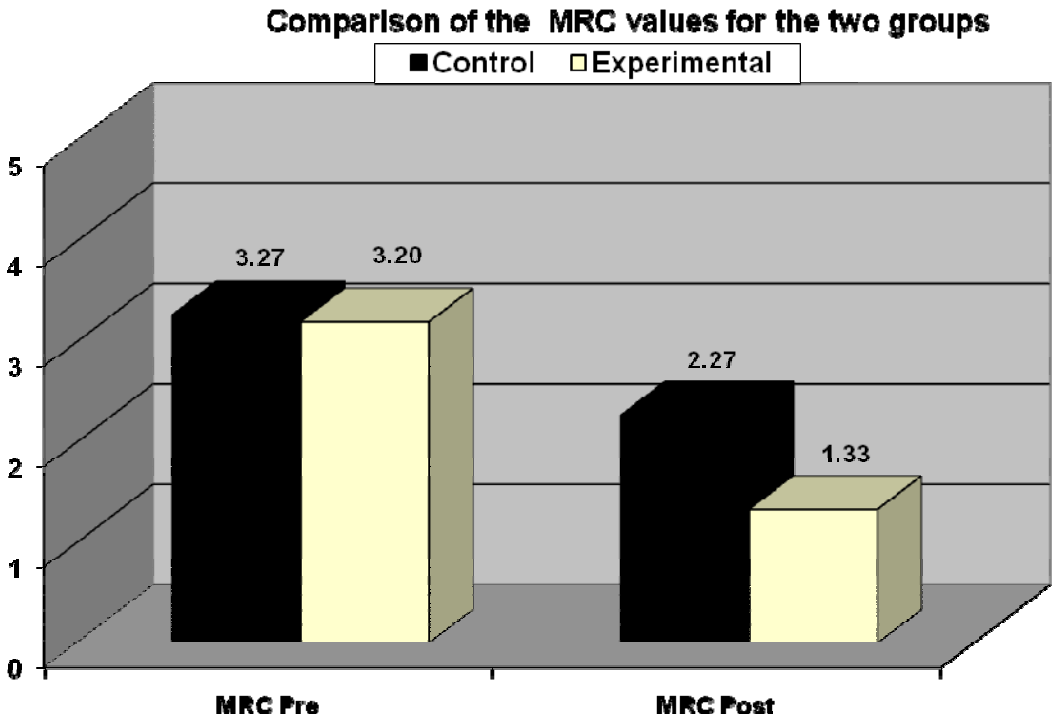

Fig 1-shows the comparison of MRC values of both groups. The pre test of control group is 3.27 and post test score is 2.27 and pre test score of experimental group is 3.20 and pre test score is 1.33

There is significant difference between the pre and post MRC values at 5 % level of significance. The post MRC values are less than the pre MRC values.

ANALYSIS OF PRE AND POST PEFR SCORES OF CONTROL GROUP USING PAIRED‘t’ TEST

TABLE 5

Group	N	PEFR SCORE				T
		Mean		SD		
		Pre	Post	Pre	Post	
Control	15	308.33	337.67	13.184	16.132	19.138

Mean pre test score for control group is 308.33 and mean post test score for control group is 337.67.”t” value obtained is 19.138.which is statistically significant at 5% level. Hence the pre PEFR differs significantly from post PEFR at 5% level of significance. Post PEFR scores are greater than the corresponding pre PEFR scores at 5% level of significance. Data analysis shows significant improvement in expiratory flow rates in control group .This might be due to cumulative effect of conventional physiotherapy.

ANALYSIS OF PRE AND POST PEFR SCORES OF EXPERIMENTAL GROUP USING PAIRED‘t’ TEST

TABLE 6

Group	N	PEFR SCORES				T
		Mean		SD		
		Pre	Post	Pre	Post	
Control	15	308.67	378.67	12.743	18.657	32.911

Mean pre test score for experimental group 308.67 and mean post test score for experimental group 378.67.”t” value obtained is 32.911.which is statistically significant at 5% level. The pre PEFR score differs significantly from post PEFR scores at 5% level of significance. Post PEFR scores are greater than the pre PEFR values at 5% level of significance. Data analysis shows significant improvement in pulmonary expiratory flow rates in experimental groups. This might be due to the cumulative effect of acapella along with conventional physiotherapy.

GRAPH 2

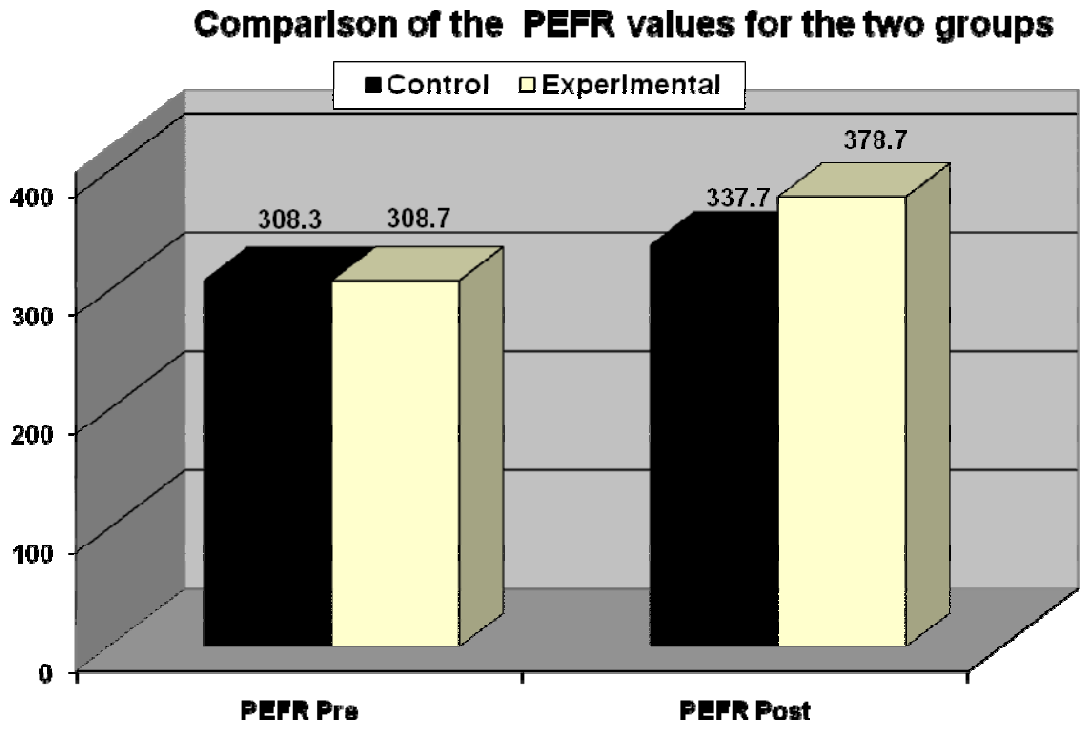

Fig-2 shows that comparison of PEFR values of both group's .The pre test score of control group is 308.33 and post test score is 337.7 and pre test score of experimental group is 308.7 and post test score is 378.7 There is significant difference between the pre and post PEFR values at 5% level of significance .The post PEFR values are significantly greater than the pre PEFR values.

CHAPTER VI

DISCUSSION

The present study was a comparative experimental approach to find out the "Effectiveness of acapella along with conventional physiotherapy in improving lung function in patients with chronic asthma."

Thirty subjects who fulfilled the inclusion criteria were randomly assigned into Group A and Group B of 15 subjects each. The sample was selected using non-probability convenient sampling technique. Here Group A receives conventional physiotherapy treatment which includes education, breathing Exercises, coughing, relaxation positioning, chest mobility exercises, and breath control techniques. Group B receives treatment with oscillatory positive expiratory pressure device - acapella along with conventional physiotherapy. The population for the study taken was chronic asthma patients using the chronic asthma questionnaire, residing in kottayam. The sample for the study was chronic asthma patients who attended the Department of Pulmonology, SH Medical Centre, Kottayam.

The total treatment was given for 6 days a week for 3 weeks, the duration of each treatment session consisted of sixty minutes for experimental group and forty minutes for control group. The outcome measures selected were peak expiratory flow meter and the medical research council dyspnoea Scale; both groups were measured on the first and last day of the treatment.

On statistical analysis of breathlessness and expiratory flow rates were done within the groups. Both the groups showed significant improvement in the expiratory flow rates and dyspnoea. Post-test analysis of control and experimental group shows statistically significant improvement in the expiratory flow rates and in breathlessness.

In chronic asthma there may be persistent findings of hyperinflation with increase in TLC, reduced FEV1\FVC and VC. Dyspnoea, or laboured breathing, is associated with tachypnoea, or rapid breathing, as the patient attempts to maintain minute ventilation in the face of severe expiratory obstruction

.

The airways widen normally during inspiration to allow the inflow of air. In asthma the normal airway narrowing during expiration is accentuated by obstruction, which prevents normal expiration. Gas that cannot be removed during expiration begins to accumulate in the lungs and hyperinflation is the result. Secondary or obstructive atelectasis is a common finding in patients with pulmonary disorders. Airway obstruction caused by copious or inspissated secretions, severe bronchial smooth muscle spasm, or significant edema of the bronchial wall in patients with chronic obstructive lung disease are capable of producing obstructive atelectasis. When complete obstruction is encountered in a bronchus that supplies air to a normally perfused area of lung parenchyma, the gas within the alveoli distal to the obstruction is absorbed into the pulmonary circulation. This process of absorption takes several hours or more. Once all alveolar gas has been absorbed into the circulation, the alveoli, now devoid of gas, collapse in a fashion similar to a balloon that has lost its air.

Improvement in the expiratory flow rates and in breathlessness in the control group might have been due to breathing exercises, chest mobility exercises, and relaxation positioning and breath control during walking.

Pursed lip breathing is thought to ease the work of breathing and shortness of breath. One theory benefits from pursed lip breathing is that, by providing slight resistance to expiration, the increased positive pressure generated within the airways helps to keep open or stent the bronchioles that otherwise collapse owing to loss of support associated with lung tissue destruction. This breathing pattern significantly decreased the respiratory rate and increased the tidal volume.

Thoracic mobility exercises combine active movements of the trunk or extremities with deep breathing. These exercises combine stretching of the trunk muscles with deep breathing which improve ventilation. Chest mobilization exercises are also used to reinforce or emphasize the depth of inspiration or controlled expiration. A patient can improve expiration by leaning forward at the hips or flexing the spine as he or she breathes out. This pushes the viscera superiorly into the diaphragm and further reinforces expiration.

Relaxation is a well established as a therapy for asthma and is valued by patients; showed objective benefit by improved peak flow readings.

Relaxation positioning will optimize the length tension status of the diaphragm .When the patient is sitting or standing, leaning forward or side lying, the abdominal contents raise the anterior part of the diaphragm, probably facilitating its contraction during inspiration. This effect, combined with relaxation of the head, neck and shoulder promotes the pattern of breathing control.

Breath control is also used to improve exercise tolerance in breathless patients. The simple technique of relaxing the arms and shoulders, reducing the walking speed a little and using the pattern of breathing in on climbing one step and breathing out on climbing the next step can lead to a marked reduction in breathlessness and the ability to converse.

The significant improvement in pulmonary function in experimental group over control group might be due to the effect of addition of oscillatory positive expiratory pressure device - acapella to the conventional treatment.

Acapella is a small hand held device that combines the benefits of both positive expiratory pressure therapy and airway vibrations to mobilize pulmonary secretions. Acapella uses a counter weighted plug and magnet which directs exhaled air through a pivoting cone, to generate airflow vibrations between 0-30Hz.Both the vibrations frequency, and the resistive pressures are adjustable. Acapella combines the features of resistive pressure device and vibratory pressure device. Resistive pressure device works by using a pressurized breath to splint open the airway. Vibratory devices work by using oscillatory vibrations that travel into the lungs, shaking free mucus plugs that the patient can cough up. When the oscillation frequency approximates the resonance frequency of the pulmonary system, endobronchial pressure oscillations are amplified and results in vibrations of the airways. These vibrations loosen mucus from airway walls.

Exhalations through these devices generate oscillations of positive expiratory pressure in the airways and repeated accelerations of expiratory airflow that have been shown to result in improved sputum clearance.

With the positive expiratory pressure on the peripheral airways and collateral channels, the increase in lung volume may allow air to get behind secretions blocking the small airways, and assist in mobilizing them. It was noticed that the use of acapella device, decreased the sputum viscosity significantly overtime, such decrease in viscosity, facilitates airway reopening since a lower pressure is needed for this with a shorter time to achieve airway opening. Oscillations of positive airway pressure ventilation maintain open airways and enhance aeration to obstructed regions of the lung**.**

Better oxygenation secondary to improved ventilation and reduced volume of trapped gas by using oscillatory positive expiratory pressure for chest physical therapy was reported.

After conventional chest physical therapy there was significant improvement in the expiratory flow parameters and dyspnoea scores, whereas with the addition of acapella device there was a highly significant improvement in these parameters. This could be attributed to improved airways patency, promotion of airflow to and from previously obstructed airways and a resultant enhancement in mucus clearance from these areas. The acapella as well has shown to enhance collateral ventilation through pores of Kohn and the channels of Lambert .The positive back pressure generated during the use of acapella allows airflow to enter these channels behind areas of mucus obstruction, keeping the airways open during exhalation. This caused significant increase in effective ventilation, providing more alveolar area for distribution of inspired air, decreasing dead space and hence the pressures will be reduced and the compliance will increase.

The acapella has shown to provide a combined effect of oscillatory vibrations and positive expiratory pressure. The theoretical benefits of positive pressure is the ability to enhance and promote mucus clearance by either preventing airway collapse by stenting the airways and increasing intrathoracic pressure distal to the retained

secretions by collateral ventilation. The use of OPEP technique was first described in Switzerland; it combines the above benefits of positive expiratory pressure with airway vibrations and oscillations. The theoretical benefits of OPEP have been described as a two fold increase in airway clearance. Indeed oscillations decrease the viscoelastic properties of mucus plugs, which make them easier to mobilize and create short bursts of increased expiratory airflow that assist in clearing secretions. In peripheral lung, where mucus plugs may block off the small airways and hence prevent normal ventilation of the alveolar gas exchange units, air movement may occur via the pores of Kohn.

Acapella does not require gravity to work and will therefore work at any angle, so it can be used in positions comfortable to the patient. Acapella can also be used in postural drainage positions.

Oral devices that apply positive end expiratory pressure maintain the patency of the airway during exhalation and accomplish many of the same goals as postural drainage in a shorter time and with less discomfort.

According to Wegener et al (2003), any relatively effective method that is preferred by the patient may increase participation in routine airway clearance .Several published studies with small patient populations and of short duration has demonstrated oscillatory positive expiratory therapy to be equivalent to chest physiotherapy.

CHAPTERVII

RESULT

The purpose of the comparative experimental study was to examine the effectiveness of the acapella device and conventional physiotherapy to improve lung function in patients with chronic asthma. The population included the patients diagnosed as chronic asthma. Those patients were randomly assigned into control group and experimental group of 15 each. Control group received conventional physiotherapy including breathing exercises, education, relaxation techniques, chest mobility exercises, and breath control during walking. The experimental group received acapella in addition to conventional physiotherapy. Pre-test evaluation was done on the first day prior to treatment and post test evaluation was done on the last day of treatment. The tools selected for measuring the outcome of the study were MRC dyspnoea scale and peak expiratory flow rate.

The results obtained was statistically analyzed using Mann- Whitney ' U' Test, Two Sample 't' Test, Paired 't' Test, and Wilcoxon signed rank test. The result showed that experimental group had a significant improvement in expiratory flow rates and reduce breathlessness than the control group.

While comparing the post test PEFR values of control group and experimental group using two – sample't' test, the calculated value is, 6.438 which is statistically significant to 0.05 significance level and comparing the post MRC values of control and experimental group using Mann-Whitney U test Z value is 3.609 which is significant to 0.05 significance level since the alternative hypothesis is accepted which shows that there exists a significant difference between the post test values of two groups.

When comparing the mean values of both, post test mean value of control group 337.67 using PEFR experimental group 378.67 using PEFR there is significant improvement, which confirms that experimental group shows significant improvement than control group.

When comparing post MRC values using Wilcoxon Signed rank test the control group Z value is 3.873 and experimental group is 3.690, there is significant

difference between the post values, which confirms that experimental group shows improvement than control group.

Results obtained from statistical analysis between pre test and post test values of experimental group at 5% level of significant showed significant improvement in PEFR values and MRC Scale following Acapella and conventional physiotherapy. These results suggest that Acapella along with conventional physiotherapy is effective in reducing dyspnea and improving lung function.

Since the alternative hypothesis is accepted Acapella along with conventional physiotherapy is more effective than conventional physiotherapy in improving lung function in patients with chronic asthma

The result of the present study revealed that both groups demonstrated significant improvement in pulmonary function, but it was more noted in experimental group who received treatment with oscillatory positive expiratory pressure device. Hence the result can be summarized as treatment with acapella along with conventional therapy is effective in improving pulmonary function and reducing dyspnoea in patients with chronic asthma.

CHAPTER VIII

CONCLUSION

The study proves that the acapella device is more effective than conventional physiotherapy alone in improving lung function and breathlessness in patients with chronic asthma. So acapella along with conventional physiotherapy can be used as an effective treatment programme in chronic asthma .Thus patients can improve their quality of life.

Hence taking into account the positive results of the study it can be concluded that the acapella device can be self-administrative, is cost effective and can be used in any reclined positions in the management of chronic asthma patients.

CHAPTER IX

LIMITATIONS AND SUGGESTIONS

Limitations

1. Size of the sample was very small which might have affected the outcome.
2. The study was of short duration.
3. Frequency of attacks was not recorded.
4. It was not able to assess the other psychological aspects of the patients.

Suggestions

1. A large sample size is required to establish the effect of treatment.
2. To make the result more valid, a long term study may be carried out.
3. Regular follow up program can be included to know the long term effect of treatment.
4. Similar study can be conducted, to know the effectiveness of oscillatory positive expiratory pressure device (acapella) in patients with other COPD; using appropriate outcome measures.
5. Study can be conducted by using different outcome measures like FEV1, FVC, and FEV 1\FVC ratio, to evaluate the reliability of oscillatory positive expiratory pressure device -acapella in improving pulmonary function in patients with chronic asthma.

CHAPTER X

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CHAPTERXII

APPENDIX

APPENDIX – 1

CASE ASSESSMENT PROFORMA

CASE SHEET NO :

NAME :

AGE :

SEX :

ADDRESS :

CHIEF COMPLIANT :

PAST MEDICAL HISTORY :

PRESENT MEDICAL HISTORY :

PERSONAL HISTORY :

ON OBSERVATION :

ON EXAMIATION :

DIAGNOSIS :

MODE OF EXERCISE :

MEASUREMENT TOOL :

MRC SCALE	
PRE TEST	**POST TEST**

PEAK EXPLARATORY RATE	
PRE TEST	**POST TEST**

Signature of physical therapy student

APPENDIX – II

PATIENT CONSENT FORM

TITLE: A COMPARATIVE STUDY ON EFFECTIVENESS OF ACAPELLA ON IMPROVING LUNG FUNCTION IN CHRONIC ASTHMA

INVESTIGATOR: _ _ _ _ _ _ _ _ _ _ _

PURPOSE OF THE STUDY:

I_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ ,have been informed that this study will work towards achieving on the functional activities of daily living in post-stroke conditions for me and other patients.

PROCEDURE:

Each term of the study protocol has been explained to me in detail. I understand that during the procedure, I will be receiving the treatment for one time a day. I understand that I will have to take this treatment for four weeks.

I understand that this will be done under investigator, _ _ _ _ _ _ _ _ _ _ _ _ _ _ supervision. I am aware also that I have to follow therapist's instructions as has been told to me.

CONFIDENTIALITY:

I understand that medical information provided by this study will be confidential. If the data are used for publication in the medical literature or for teaching purposes, no names will be used and other literature such as audio or video tapes will be used only with permission.

RISK AND DISCOMFORT:

I understand that there are no potential risks associated with this procedure, and understand that investigator will accompany me during this procedure. There are no known hazards associated with this procedure.

REFUSAL OR WITHDRAWL OF PARICIPATION:

I understand that the decision my participation is wholly voluntary and I may refuse participate, may withdraw consent at any time during the study.

I also understand that the investigator may terminate my participation in the study at anytime after researcher has explained me the reasons to do so.

I _ _ _ _ _ _ _ _ _ _ _ _ _ _ have explained to ……. the purpose of the research, the procedures required and the possible risks and benefits, to the best of my ability.

…… ……

Investigator Date

I ……. Confirm that researcher has explained me the purpose of the research, the study procedure and the possible risks and benefits that I may experience. I have read and I have understood this consent to participate as a subject in this research project.

…….. ……

Subject Date

…….. …….

Signature of the Witness Date

APPENDIX- III

THE MEDICAL RESEARCH COUNCIL DYSPNOEA SCALE [ATS]

GRADE	
I	Not troubled by breathlessness except on strenuous exercises
2	Short of breath when hurrying on the level or walking up a slight hill
3	Walk slower than people of the same age on the level because of breathlessness or have to stop for breath when walking at own pace on the level
4	Stops for breath after walking about 100 yards or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when undressing

Strenuous Exercises: Activities that includes difficult tasks like lifting heavy weights, walking up hill, stair climbing, playing sports, bicycling, jogging etc.

ATS- American Thoracic Society

APPENDIX -IV

CHRONIC ASTHMA QUESTIONNAIRE

Name: **Age:** **Sex:**

QUESTION	RESPONSE CHOICES
1. Have you had wheezing or whistling in your chest at any time?	Yes ☐ No ☐
2. Have you been woken up at night by an attack of coughing?	Yes ☐ no ☐
3. Have had an attack of shortness of breath that came on during the day when you were at rest?	Yes ☐ no ☐
4. Have you had felt breathless that came on following strenuous activity at any time?	Yes ☐ no ☐
5. Do you have any pets at home?	Yes ☐ no ☐
6. Do you have any triggering symptoms of coughing, wheezing, or shortness of breath, when exposed to dust, pollens, molds, cold air, and humidity and weather changes?	Yes ☐ No ☐
7. Do you have mucous in your chest when you cough? If you have is it usually clear---------, Discoloured----------?	Yes ☐ No ☐
8. Have you been to any pulmonologist during the last few years (lung doctor) if yes for how long you have been going?	Yes ☐ No ☐
9. Have you been using any reliever medications or inhalers or any bronchodilator drugs?	Yes ☐ No ☐
10. How old were you when you had the attack? ---------- Have you had 2 or more such episodes since then? ----------	Yes ☐ No ☐